

**COPY OF PAPERS  
ORIGINALLY FILED**

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: <b>RECEIVED</b>

AUG 30 2002

**U.S. PATENT DOCUMENTS**

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
JK	AA	4,160,152	07/03/79	Wightman et al.	219	438	12/04/78
JK	AB	4,256,108	03/17/81	Theeuwes	128	260	05/21/79
JK	AC	4,265,874	05/05/81	Bonsen et al.	424	15	04/25/80

**FOREIGN PATENT DOCUMENTS**

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATIO N (YES/NO)
		NONE					

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)**

	AD	<del>Adlereroutz and Mazur, "Phyto-estrogens and Western Diseases," Ann. Med., 29:95-120 (1997)</del>
	AE	<del>Altschul et al., "Basic Local Alignment Search Tool," J Mol. Biol., 215:403-410 (1990)</del>
	AF	<del>Baes et al., "A New Orphan Member of the Nuclear Hormone Receptor Superfamily That Interacts with a Subset of Retinoic Acid Response Elements," Molecular and Cellular Biology, 14(3):1544-1552 (1994)</del>
	AG	<del>Bahouth et al., "Immunological approaches for probing receptor structure and function," TIPS Reviews, 12:338-343 (1991)</del>
JK	AH	Bammel et al., "Divergent effects of different enzyme-inducing agents on endogenous and exogenous testosterone," 42:641-644 (1992)

EXAMINER  /James Ketter/	DATE CONSIDERED  03/07/2007
--------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

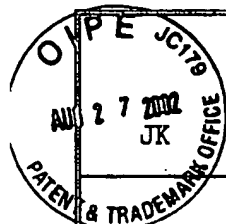
Form 1449

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,788
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643

RECEIVED

AUG 30 2002

TECH CENTER 1600/29



	AI	Barwick et al., "Trans-species Gene Transfer for Analysis of Glucocorticoid-Inducible Transcriptional Activation of Transiently Expressed Human CYP3A4 and Rabbit CYP3A6 in Primary Cultures of Adult Rat and Rabbit Hepatocytes," <i>Molecular Pharmacology</i> , 50:10-16 (1996)
	AJ	<del>Beato et al., "Steroid Hormone Receptors: Many Actors in Search of a Plot," <i>Cell</i>, 83:851-857 (1995)</del>
JK	AK	Beaune et al., "Isolation and sequence determination of a cDNA clone related to human cytochrome P-450 nifedipine oxidase," <i>Proc. Natl. Acad. Sci.</i> , 83:8064-8068 (1986)
JK	AL	Blumberg et al., "Novel retinoic acid receptor ligands in <i>Xenopus</i> embryos," <i>Proc. Natl. Acad. Sci.</i> , 93:4873-4878 (1996)
JK	AM	Blumberg et al., "BXR, an embryonic orphan nuclear receptor activated by a novel class of endogenous benzoate metabolites," <i>Genes &amp; Development</i> , 12:1269-1277 (1998)
	AN	<del>Burger et al., "Paradoxical transcriptional activation of rat liver cytochrome P-450 3A1 by dexamethasone and the antiglucocorticoid pregnenolone 16<math>\alpha</math>-carbonitrile: Analysis by transient transfection into primary monolayer cultures of adult rat hepatocytes," <i>Proc. Natl. Acad. Sci. (USA)</i>, 89:2145-2149 (1992)</del>
	AO	<del>Denison and Whitlock, "Xenobiotic-inducible Transcription of Cytochrome P450 Genes," <i>Journal of Biological Chemistry</i>, 270(31):18175-18178 (1995)</del>
	AP	<del>Devereux et al., "A comprehensive set of sequence analysis programs for the VAX," <i>Nucleic Acids Research</i>, 12:387-395 (1984)</del>
JK	AQ	Edwards et al., "Changes in Cortisol Metabolism Following Rifampicin Therapy," <i>The Lancet</i> , 2:549-551 (1974)
	AR	<del>Elchourbagy and Guzelian, "Separation, Purification, and Characterization of a Novel Form of Hepatic Cytochrome P-450 from Rats Treated with Pregnenolone 16<math>\alpha</math>-carbonitrile," <i>Journal of Biological Chemistry</i>, 255:1279-1285 (1980)</del>
	AS	<del>Enmark and Gustafsson, "Orphan Nuclear Receptors: The First Eight Years," <i>Mol. Endo.</i>, 10(11):1293-1307 (1996)</del>

EXAMINER /James Ketter/	DATE CONSIDERED 03/07/2007
----------------------------	-------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

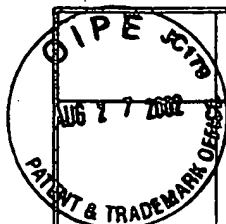
**COPY OF PAPERS  
ORIGINALLY FILED**

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643

**RECEIVED**

**AUG 30 2002**

**TECH CENTER 1600/29**



	AT	<del>Evans, Ronald M., "The Steroid and Thyroid Hormone Receptor Superfamily," <i>Science</i>, 240:889-895 (1988)</del>
	AU	<del>Fernandez-Salguero and Gonzalez, "The CYP2A gene subfamily: species differences, regulation, catalytic activities and role in chemical carcinogenesis," <i>Pharmacogenetics</i>, 5:3123-3128 (1995)</del>
	AV	<del>Forman et al., "Unique Response Pathways Are Established by Allosteric Interactions among Nuclear Hormone Receptors," <i>Cell</i>, 81:541-550 (1995)</del>
	AW	<del>Forman et al., "Hypolipidemic drugs, polyunsaturated fatty acids, and eicosanoids are ligands for peroxisome proliferator-activated receptors <math>\alpha</math> and <math>\delta</math>," <i>Proc. Natl. Acad. Sci. USA</i>, 94:4312-4317 (1997)</del>
	AX	<del>Gonzalez et al., "Complete cDNA and Protein Sequence of a Pregnenolone 16<math>\alpha</math>-Carbonitrile-induced Cytochrome P-450," <i>Journal of Biological Chemistry</i>, 260(12):7435-7441 (1985)</del>
	AY	<del>Gonzalez et al., "Pregnenolone 16<math>\alpha</math>-Carbonitrile Inducible P-450 Gene Family: Gene Conversion and Differential Regulation," <i>Molecular and Cellular Biology</i>, 6(8):2969-2976 (1986)</del>
JK	AZ	Gonzalez, Frank J., "Human cytochromes P450: problems and prospects," <i>TIPS Reviews</i> , 13:346-352 (1992)
	BA	<del>Gottlicher et al., "Fatty acids activate a chimera of the clofibrate acid-activated receptor and the glucocorticoid receptor," <i>Proc. Natl. Acad. Sci. USA</i>, 89:4653-4657 (1992)</del>
JK	BB	Guengerich, F. Peter, "Metabolism of 17 $\alpha$ Ethynylestradiol in Humans", <i>Life Sciences</i> , 47:1981-1988 (1990)
	BC	<del>Hankinson, Oliver, "The Aryl Hydrocarbon Receptor Complex," <i>Annu. Rev. Pharmacol. Toxicol.</i> 35:307-340 (1995)</del>
	BD	<del>Hardwick et al., "Cloning of DNA Complementary to Cytochrome P-450 Induced by Pregnenolone-16<math>\alpha</math>carbonitrile," <i>Journal of Biological Chemistry</i>, 258:10182-10186 (1983)</del>

EXAMINER  /James Ketter/	DATE CONSIDERED  03/07/2007
--------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643

RECEIVED

AUG 30 2002

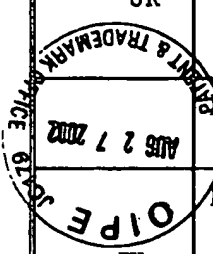
TECH CENTER 1600/2

O I P E AUG 27 2002 PATENT & TRADEMARK OFFICE	BE	<del>Henikoff and Henikoff, "Amino acid substitution matrices from protein blocks," <i>Proc. Natl. Acad. Sci. USA</i>, 89:10915-10919 (1992)</del>
	BF	<del>Heuman et al., "Immunohistochemical Evidence for Induction of a Common Form of Hepatic Cytochrome P-450 in Rats Treated with Pregnenolone-16<math>\alpha</math>-carbonitrile or other Steroidal or Non-Steroidal Agents," <i>Molecular Pharmacology</i>, 21:753-760 (1982)</del>
	BG	<del>Hollenberg et al., "Primary structure and expression of a functional human glucocorticoid receptor cDNA," <i>Nature</i>, 318(6047):635-641 (1985)</del>
JK	BH	Hollenberg et al., "Colocalization of DNA-Binding and Transcriptional Activation Functions in the Human Glucocorticoid Receptor," <i>Cell</i> , 49:39-46 (1987)
JK	BI	Holtbecker et al., "The Nifedipine-Rifampin Interaction: Evidence for Induction of Gut Wall Metabolism," <i>Drug Metabolism and Disposition</i> , 23(10):1121-1123 (1996)
	BJ	<del>Jonat et al., "Antitumor Promotion and Antiinflammation: Down-Modulation of AP-1 (Fos/Jun) Activity by Glucocorticoid Hormone," <i>Cell</i>, 62:1189-1204 (1990)</del>
	BK	<del>Juchau, M.R., "Substrate Specificities and Functions of the P450 Cytochromes," <i>Life Sciences</i>, 47:2385-2394 (1990)</del>
JK	BL	Kliwer et al., "Fatty acids and eicosanoids regulate gene expression through direct interactions with peroxisome proliferator-activated receptors $\alpha$ and $\gamma$ ," <i>Proc. Natl. Acad. Sci. USA</i> , 94:4318-4323 (1997)
JK	BM	Kliwer et al., "An Orphan Nuclear Receptor Activated by Pregnanes Defines a novel Steroid Signaling Pathway," <i>Cell</i> , 92:73-82 (1998)
JK	BN	Kolars et al., "First-pass metabolism of cyclosporin by the gut," <i>Lancet</i> , 338:1488-1490 (1991)
JK	BO	Kolars et al., "Identification of Rifampin-inducible P450III A4 (CYP3A4) in Human Small Bowel Enterocytes," <i>Journal of Clinical Investigation, Inc.</i> , 90:1871-1878 (1992)
JK	BP	Kyriazopoulou et al., "Rifampicin-Induced Adrenal Crisis In Addisonian Patients Receiving Corticosteroid Replacement Therapy," <i>Journal of Clinical Endocrinology and Metabolism</i> , 59(6):1204-1206 (1984)

EXAMINER /James Ketter/	DATE CONSIDERED 03/07/2007
----------------------------	-------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

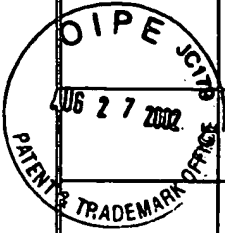
FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227, <b>RECEIVED</b>
	Applicant(s): Ronald M. Evans <b>AUG 30 2002</b>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit <b>TECH CENTER 1600/2901</b>

JK	BQ	Kyriazopoulou and Vagenakis, "Abnormal Overnight Dexamethasone Suppression Test in Subjects Receiving Rifampicin Therapy," <i>Journal of Clinical Endocrinology and Metabolism</i> , 74(1):315-317 (1992)
	BR	<del>Ladiaz and Karathanasis, "Regulation of the Apolipoprotein AI Gene by ARP-1 a Novel Member of the Steroid Receptor Superfamily," <i>Science</i>, 251:561-565 (1991)</del>
JK	BS	Lee et al., "Time course of the changes in prednisolone pharmacokinetics after co-administration or discontinuation of rifampin," <i>Eur. Journal of Clinical Pharmacology</i> , 45:287-289 (1993)
JK	BT	Li and Evans, "Ligation independent cloning irrespective of restriction site compatibility," <i>Nucleic Acids Research</i> , 25:4165-4166 (1997)
JK	BU	Lonning et al., "Plasma Levels of Estradiol, Estrone, Estrone Sulfate and Sex Hormone Binding Globulin in Patients Receiving Rifampicin," <i>J. Steroid Biochem.</i> , 33(4A):631-635 (1989)
	BV	<del>Mangelsdorf et al., "The Nuclear Receptor Superfamily: The Second Decade," <i>Cell</i>, 83:835-839 (1995)</del>
	BW	<del>Mangelsdorf and Evans, "The RXR Heterodimers and Orphan Receptors," <i>Cell</i>, 83:841-850 (1995)</del>
JK	BX	McAllister et al., "Rifampicin reduces effectiveness and bioavailability of prednisolone," <i>British Medical Journal</i> , 286:923-925 (1983)
	BY	<del>Miyata et al., "Transcriptional Elements Directing a Liver Specific Expression of P450/6BA (CYP3A2) Gene Encoding Testosterone 6β-Hydroxylase," <i>Archives of Biochemistry and Biophysics</i>, 318(1):71-79 (1995)</del>
	BZ	<del>Melowa et al., "Complete cDNA sequence of a cytochrome P-450 inducible by glucocorticoids in human liver," <i>Proc. Natl. Acad. Sci. USA</i>, 83:5311-5315 (1986)</del>
	CA	<del>Nebert, Daniel W., "P450 Genes: Structure, Evolution, and Regulation," <i>Ann. Rev. Biochem.</i>, 56:945-993 (1987)</del>

EXAMINER  /James Ketter/	DATE CONSIDERED  03/07/2007
--------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643

	CB	<del>Needleman and Wunsoh, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," <i>Journal of Molecular Biology</i>, 48:443-453 (1970)</del>
	CC	<del>O'Malley and Connolly, "Orphan Receptors: In Search of a Unifying Hypothesis for Activation," <i>Molecular Endocrinology</i>, 6:1539-1561 (1992)</del>
	CD	<del>Ogura and Evans, "A retinoic acid triggered cascade of HOXB1 gene activation," <i>Proc. Natl. Acad. Sci. USA</i>, 92:387-391 (1995)</del>
JK	CE	Ohnhaus et al., "Urinary Excretion of 6 $\beta$ -Hydroxycortisol and the Time Course Measurement of Enzyme Induction in Man," <i>Eur. J. Clin. Pharmacol.</i> , 36:39-46 (1989)
	CF	<del>Quattrochi et al., "A Novel cis-Acting Element in a Liver Cytochrome P450 3A Gene Confers Synergistic Induction by Glucocorticoids plus Antiglucocorticoids," <i>Journal of Biological Chemistry</i>, 270 (40):28917-28923 (1995)</del>
	CG	<del>Russel and Wilson, "Steroid 5<math>\alpha</math> Reductase: Two Genes/Two Enzymes," <i>Annu. Rev. Biochem.</i>, 63:25-61 (1994)</del>
	CH	<del>Schuetz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver," <i>Journal of Biological Chemistry</i>, 259(3):1999-2006 (1984)</del>
	CI	<del>Schuetz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver," <i>Journal of Biological Chemistry</i>, 259(3):2007-2012 (1984)</del>
	CJ	<del>Schule et al., "Functional Antagonism between Oncoprotein c-Jun and the Glucocorticoid Receptor," <i>Cell</i>, 62:1217-1226 (1990)</del>
	CK	<del>Selye, H., "Hormones and Resistance," <i>Journal of Pharmaceutical Sciences</i>, 60(1):1-28 (1971)</del>
	CL	<del>Sucov et al., "Characterization of an autoregulated response element in the mouse retinoic acid receptor type <math>\beta</math> gene," <i>Proc. Natl. Acad. Sci. USA</i>, 87:5392-5396 (1990)</del>
	CM	<del>Staden, Rodger, "The current status and portability of our sequence banding software," <i>Nucleic Acids Research</i>, 14(1):217-231 (1986)</del>

EXAMINER /James Ketter/	DATE CONSIDERED 03/07/2007
----------------------------	-------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

AUG 30 2002

Form 1449

TECH CENTER 1600/2900

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643

JK	CN	Terzolo et al., "Misdiagnosis of Cushing's Syndrome in a Patient Receiving Rifampicin Therapy for Tuberculosis," <i>Horm. Metab. Res.</i> , 27:148-150 (1995)
JK	CO	<del>Umesono et al., "Direct Repeats as Selective Response Elements for the Thyroid Hormone, Retinoic Acid, and Vitamin D<sub>3</sub> Receptors," <i>Cell</i>, 65:1255-1266 (1991)</del>
JK	CP	Watkins et al., "Erythromycin Breath Test as an Assay of Glucocorticoid-inducible Liver Cytochromes P-450," <i>J. Clin. Invest.</i> , 83:688-697 (1989)
JK	CQ	Wietholtz et al., "Stimulation of bile acid 6 $\alpha$ -hydroxylation by rifampin," <i>Journal of Hepatology</i> , 24:713-718 (1996)
	CR	<del>Willy et al., "LXR, a nuclear receptor that defines a distinct retinoid response pathway," <i>Genes &amp; Development</i>, 9:1033-1045 (1995)</del>
JK	CS	Wurtz et al., "A canonical structure for the ligand-binding domain of nuclear receptors," <i>Nature Structural Biology</i> , 3:87-94 (1996)
	CT	<del>Yang-Yen et al., "Transcriptional Interference between c-Jun and the Glucocorticoid Receptor: Mutual Inhibition of DNA Binding Due to Direct Protein-Protein Interaction," <i>Cell</i>, 62:1205-1215 (1990)</del>
JK	CU	Zawawi et al., "The Effects of Therapy with Rifampicin and Isoniazid on Basic Investigations for Cushing's Syndrome," <i>Ir. j. Med. Sci.</i> , 165:300-302 (1996)

COPY OF PAPERS  
ORIGINALLY FILED

RECEIVED

AUG 30 2002

TECH CENTER 1600/2900

EXAMINER /James Ketter/	DATE CONSIDERED 03/07/2007
-------------------------	----------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office	<b>Docket No. (Optional)</b> SALK2270-2	<b>Serial No.:</b> 09/458,366
	<b>Applicant(s):</b> EVANS ET AL	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>Filing Date:</b> DECEMBER 9, 1999	<b>Group Art Unit:</b> 1632

### U.S. PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE

### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	<del>99/19334</del>	<del>22APR99</del>	<del>WO</del>	<del>6</del>		
	<del>99/61622</del>	<del>2DEC99</del>	<del>WO</del>	<del>6</del>		
	<del>99/489915</del>	<del>22SEP99</del>	<del>WO</del>	<del>6</del>		

**RECEIVED**  
AUG 30 2002  
TECH CENTER 1600/2900

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)


COPY OF PAPERS  
ORIGINALLY FILED

<b>EXAMINER</b> /James Ketter/	<b>DATE CONSIDERED</b> 03/07/2007
-----------------------------------	--------------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449

Gray Cary\GT\6211938.1  
62574-159106